

REMARKS/ARGUMENTS

Claims 1, 4, 5, 7 to 23 and 26 were previously pending with claim 4 standing withdrawn. Claim 4 is canceled without prejudice. Claims 1 and 14 are presently amended. After entry of these amendments, claims 1, 5, 7 to 23 and 26 will be pending.

Claims 1, 5 and 7-13 under 35 U.S.C. 112, first paragraph, continue to be rejected for an alleged failure to comply with the written description requirement was maintained.

Claims 1, 5, 7-11, 14-16, 18-23 and 26 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent number 5,955,075.

Claims 1, 5, 7-11, 14-16, 18-23 and 26 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by WO 95/34650 (published December 21, 1995).

Claims 1, 5, 7-23 and 26 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent number 5,955,075 (issued September 21, 1999) IDS reference 11 submitted March 31, 2005), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001).

Claims 1, 5, 7-23 and 26 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 95/34650 (published December 21, 1995), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1 657, March 15, 2001).

Support for the amendments to the claims

Claim 1 was amended to set forth SEQ ID NO:2 and claims 1 and 14 were amended to set forth subject matter related to providing a therapy for the subject or providing a prognosis for the subject based upon the correlation. Support for this subject matter is found in the specification *inter alia* at paragraph 10.

Accordingly, the Applicants believe the amendments to the claims add no new matter and respectfully request their entry.

Response to the rejection of claims 1, 5 and 7-13 under 35 U.S.C. 112, first paragraph, for alleged failure to comply with the written description requirement was maintained.

Without acquiescing on the merits and in the spirit of expediting examination, the Applicants have amended claim 1 to set forth the human carbonic anhydrase IX (CAIX) protein of SEQ ID NO:2. Accordingly, the Applicants respectfully request that the above grounds for rejection be reconsidered and withdrawn.

Response to the rejection of claims 1, 5, 7-11, 14-16, 18-23 and 26 under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent number 5,955,075.

The rejection appears to have been predicated, at least in part, upon disregarding the "correlating" step of the base claims. Without acquiescing on the merits and in the spirit of expediting prosecution, the applicants have amended the base claims to set forth the further step of "*(c) providing a therapy for the subject or providing a prognosis for the subject based upon the correlation.*"

Further with regard to the correlation's quantification percentage subject matter, the Applicants note again that, as the '075 patent teaches MN as a putative oncogene (*see*, '075 patent at col. 4, lines 5 to 9), the skilled person would understand that for diagnosis, high levels of CAIX may imply a high probability of renal cell carcinoma and that the higher the level of expressed CAIX present, the more damage is done. However the claims of the present application are all drawn to methods of prognosis (*i.e.*, forecasting the probable outcome of the disease state) based upon the present inventors' discovery that unexpectedly high levels of CAIX indicated a *better*, not worse, chance for recovery. This particular surprising relationship and its practical application in therapy was not taught or suggested in the cited art.

Accordingly, the Applicants respectfully request that the above grounds for rejection be reconsidered and withdrawn.

Response to the rejection of claims 1, 5, 7-11, 14-16, 18-23 and 26 under 35 U.S.C. 102(b) as allegedly being anticipated by WO 95/34650.

The rejection appears to have been predicated, at least in part, upon disregarding the "correlating" step of the base claims. Without acquiescing on the merits and in the spirit of expediting prosecution, the applicants have amended the base claims to set forth the further step

of "(c) *providing a therapy for the subject or providing a prognosis for the subject based upon the correlation.*"

Further with regard to the correlation subject matter, the Applicants note again that, as the WO 95/34650 publication teaches MN as a putative oncogene (*see*, first line of the Abstract, the skilled person would understand that for diagnosis, high levels of CAIX may imply a high probability of renal cell carcinoma and that the higher the level of expressed CAIX present, the more damage is done. However the claims of the present application are all drawn to methods of prognosis (i.e., forecasting the probable outcome of the disease state) based upon the present inventors' discovery that unexpectedly high levels of CAIX indicated a *better*, not worse, chance for recovery. This particular surprising relationship and its practical application in therapy was not taught or suggested in the cited art.

Accordingly, the Applicants respectfully request that the above grounds for rejection be reconsidered and withdrawn.

Response to the rejection of claims 1, 5, 7-23 and 26 under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent number 5,955,075 (issued September 21, 1999) IDS reference 11 submitted March 31, 2005), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1657, March 15, 2001.

Zisman et al. teach an integrated staging system for prognostication of renal cell carcinoma. They do not mention CAIX. The Examiner contends a reasonable expectation of success would be present in the proposed combination. As noted above, the expectation would have been that an increased CAIX expression would have been associated with the worse prognosis. Here, the claims set forth just the *opposite* relationship. As the instant invention is not a case where prior art elements were combined according to known methods to yield *predictable* results (*see*, MPEP §2143), the Applicants respectfully request that this grounds of rejection be reconsidered and withdrawn.

Response to the rejection of claims 1, 5, 7-23 and 26 under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 95/34650 (published December 21, 1995), and further in view of Zisman et al. (Journal of Clinical Oncology 19(6): 1649-1 657, March 15, 2001.

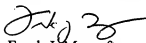
Zisman et al. teach an integrated staging system for prognostication of renal cell carcinoma. They do not mention CAIX. The Examiner contends a reasonable expectation of success would be present in the proposed combination. As noted above, the expectation would have been that an increased CAIX expression would have been associated with the worse prognosis. Here, the claims set forth just the *opposite* relationship. As the instant invention is not a case where prior art elements were combined according to known methods to yield *predictable* results (see, MPEP §2143), the Applicants respectfully request that this grounds of rejection be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,


Frank J. Mycroft
Reg. No. 46,946

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 415-576-0300
Attachments
FJM:fjm
61713461 v1